

Notice of Allowability	Application No.	Applicant(s)	
	08/485,438	EISENBERG ET AL.	
	Examiner	Art Unit	
	William W. Moore	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTO-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. This communication is responsive to The amendment and Terminal Disclaimer filed 30 September 2004.

2. The allowed claim(s) is/are 14-22,24-34,36 and 37.

3. The drawings filed on _____ are accepted by the Examiner.

4. Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some* c) None of the:

1. Certified copies of the priority documents have been received.

2. Certified copies of the priority documents have been received in Application No. _____.

3. Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

6. CORRECTED DRAWINGS (as "replacement sheets") must be submitted.

(a) Including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached

1) hereto or 2) to Paper No./Mail Date _____.

(b) Including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

7. DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- 1. Notice of References Cited (PTO-892)
- 2. Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3. Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date 26 August 2003
- 4. Examiner's Comment Regarding Requirement for Deposit
of Biological Material
- 5. Notice of Informal Patent Application (PTO-152)
- 6. Interview Summary (PTO-413),
Paper No./Mail Date _____.
- 7. Examiner's Amendment/Comment
- 8. Examiner's Statement of Reasons for Allowance
- 9. Other _____.

[Signature]
PONRATTA PUACHUANMUTH
SUPERSEAS PATENT EXAMINER
TELEFAX: 202-205-6014

ALLOWANCE

The following is an examiner's statement of reasons for allowance:

The Amendment after Final Rejection filed September 30, 2004, canceling claims 23 and 35, amending claims 1420, 22, 24, 27-32 and 34 and adding the new claims 36 and 37 that replace the canceled claims 23 and 35 has been entered. As noted, at pages 9-11 of the Response following the claim amendments, these amendments are supported by the specification. They clarify the intended subject matter by removing superfluous descriptions, "secretory leukocyte" and "analog", where the amino acid sequence of a serine protease inhibitor described in independent claims 14 and 24 is a generic serine protease inhibitor and the dependent claims describe sequence modifications that alter its inhibitory specificity or permit, in claims 36 and 37, retention of the specificity of the inhibitor as it is found in cells and fluids of the human body.

One of the two obviousness-type double patenting rejections of record is overcome by Terminal Disclaimers designating US Patent No. 6,017,880 that were filed by both assignees of the instant application September 30, 2004. The remaining obviousness-type double patenting rejection of record is withdrawn for essentially the same reasons that a similar double patenting rejection of record, made in the application that issued as the '880 patent, over of claims now appearing US Patent No. 6,312,990, was withdrawn because the reasoning of *In re Kaplan*, 229 USPQ 678 (Fed. Cir. 1986), controls in both. In *Kaplan*, the appellate panel looked to the earlier holding of *In re Vogel* that the disclosure of the application in which an obviousness double-patenting rejection is made "may not be used as prior art in considering the question" of whether "any claim in the application defines merely an obvious variation of an invention disclosed and claimed in the patent" applied in an obviousness-type double patenting rejection. *In re Vogel*, 164 USPQ 619 (CCPA 1970), at 622. The court in *Kaplan* considered that

"dominance" or "embrace" of a claim in a patent applied in a double-patenting rejection of pending claims under the theory of "claim support" was an improper basis for analyzing double patenting. 229 USPQ at 682. The court held that while "a mere variation of that [patented] invention which would have been obvious to those of ordinary skill in the relevant art" may be involved in "obviousness-type double patenting", there must also "be some clear evidence to establish why the variation would have been obvious which can properly qualify as 'prior art'. Even if obviousness of the variation is predicated on the level of skill in the art, prior art evidence is needed to show what that level of skill was." 229 USPQ at 683.

No disclosure intervenes between the filing date of the application issuing as the '990 patent and the priority date for disclosures of the instant application represented by the instant claims, thus no evidence is available, suggesting that virologists or molecular biologists of ordinary skill in the art would have been aware that a human leukocyte protease might mediate viral infection of CD4+ cells, or that therapeutic administration of the protease inhibitor defined by the instant claims would inhibit viral proliferation by blocking viral association with such cells. Although the broad, generic, method of claim 12 of the '990 patent covers and protects, i.e., "dominates", methods of the claims that remain herein, it cannot alone be the basis for a double-patenting rejection where retrospective, prior art, evidence of obviousness is required to render practice of a method of the patented claim patentably indistinct from methods of the pending claims. Thus use in methods of the claims pending herein of the same product disclosed in the '990 patent is "**more than an obvious variation**" of a generic use of the '990 patent claim, and is "**patentably distinct from**" any method proposed for that product disclosed in the '990 patent or the prior art. *General Foods Corp. v. Studiengesellschaft Kohle mbH*, 23 USPQ2d 1839 (Fed. Cir. 1002), at 1843 (emphases in original).

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Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to William W. Moore whose telephone number is now 571.272.0933. The examiner can normally be reached between 9:00AM and 5:30PM EST. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can now be reached at 571.272.0928. The fax phone numbers for all communications for the organization where this application or proceeding is assigned remains 703.872.9306. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is now 571.272.1600.

William W. Moore
October 18, 2004